STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner

In the matter of the Home Infusion Therapy
Provider Class Plan Determination
Report pursuant to Public Act 350 of 1980
_____/ No. 11-023-BC

Issued and entered
this 22nd day of July 2011
by R. Kevin Clinton
Commissioner

ORDER ISSUING DETERMINATION REPORT

I

BACKGROUND

Pursuant to Public Act 350 of 1980, as amended (Act), being MCLA 550.1101 et seq.; MSA 24.660 (101) et seq., the Commissioner of the Office of Financial and Insurance Regulation (Commissioner) issued Order No. 11-003-BC on January 21, 2011, giving notice to Blue Cross and Blue Shield of Michigan (BCBSM), and to each person who requested a copy of such notice, of his intent to make a determination with respect to the home infusion therapy provider class plan for calendar years 2008 and 2009.

II

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Based upon the foregoing considerations it is FOUND and CONCLUDED that:

1. Jurisdiction and authority over this matter are vested in the Commissioner pursuant to the Act.

2. BCBSM has complied with all applicable provisions of the Act.

3. All procedural requirements of the Act have been met.

4. The staff reviewed relevant data pertaining to the home infusion therapy provider class plan as discussed in the attached report, including written comments received during

the input period on the provider class plan. The input period was designed to provide the public with an opportunity to present data, views, and arguments with respect to the home infusion therapy provider class plan.

5. Pursuant to Section 510(2) of the Act, a copy of the determination report and this order shall be sent to the health care corporation and each person who has requested a copy of such determination by certified or registered mail.

III

ORDER

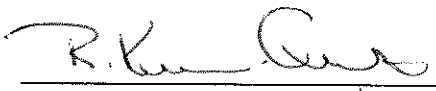
Therefore, it is ORDERED that:

1. The attached home infusion therapy provider class plan determination report shall be incorporated by reference as part of this order and shall serve as the Commissioner's determination with respect to the home infusion therapy provider class plan for the calendar years 2008 and 2009.

2. Pursuant to Section 510(2) of the Act, the Commissioner shall notify BCBSM and each person who has requested a copy of such determination by certified or registered mail.

3. Pursuant to Section 515(1) and (2), any appeal must be filed within 30 days of the date of this determination report. The request for an appeal shall identify the issue or issues involved and how the person is aggrieved.

The Commissioner retains jurisdiction of the matters contained herein and the authority to enter such further order or orders as he shall deem just, necessary and appropriate.



R. Kevin Clinton
Commissioner

RICK SYNDER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
R. KEVIN CLINTON, COMMISSIONER

STEVEN H. HILFINGER
DIRECTOR

Blue Cross and Blue Shield of Michigan's Home Infusion Therapy Provider Class Plan for calendar years 2008 and 2009

A Determination Report issued by Commissioner R. Kevin Clinton

July 2011

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HOME INFUSION THERAPY

PROVIDER CLASS PLAN

DETERMINATION REPORT

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EXECUTIVE SUMMARY

Pursuant to Public Act 350 of 1980, this report provides a review and determination of whether the arrangements Blue Cross and Blue Shield of Michigan (BCBSM) has established with health care providers have substantially achieved the access, quality of care, and cost goals set forth in the Nonprofit Health Care Corporation Reform Act for calendar years 2008 and 2009. The statutory goals specify that these arrangements, known as provider class plans, must assure subscribers reasonable access to, and reasonable cost and quality of, health care services covered under BCBSM's certificates.

The analysis and determination of goal performance is based on BCBSM's 2008-2009 home infusion therapy provider class plan annual report, additional data requested of BCBSM, and information on file with respect to this provider class plan. This material was supplemented as necessary by data from published sources. The determination report analyzes the level of achievement for each goal separately and discusses interaction and balance among the goals.

Access Goal

Achievement of the access goal requires BCBSM to be able to assure that, in any given area of the state, a BCBSM member has reasonable access to home infusion therapy (HIT) services whenever necessary. In analyzing BCBSM's performance on the access goal, consideration was given to the formal participation rates of home infusion therapy providers. Because HIT providers are not licensed by the state of Michigan, BCBSM's 100% participation rate was based on the total number of BCBSM registered HIT providers during 2008 and 2009. The lack of complaints on file with OFIR regarding the inability of BCBSM members to access home infusion therapy throughout Michigan seems to illustrate access to such services is adequate. BCBSM also demonstrated a commitment to service through the availability of easily accessible electronic publications and tools, effective provider servicing, an expansion of electronic provider enrollment and electronic funds transfer. Based on these facts, it is determined that BCBSM met the access goal during 2008 and 2009.

Quality of Care Goal

The quality of care goal requires BCBSM to assure that providers meet and abide by reasonable standards of health care quality. To achieve this goal, BCBSM must show that it makes providers aware of practice guidelines and protocols for home infusion therapy services, that it verifies that providers adhere to such guidelines and that it maintains effective methods of communication with its providers. During calendar years 2008 and 2009, BCBSM continued to ensure that its qualification standards for participation were met by HIT providers, implemented quality controls through utilization review audits to ensure that the services rendered to BCBSM patients were medically necessary and appropriately administered, and had an established appeal process to deal with provider disputes. BCBSM acknowledged that one of its "standardized" objectives listed in all provider class plans to meet with the appropriate specialty liaison society is not commonly practiced with home infusion therapy providers. BCBSM stated it will rewrite this particular

objective in the home infusion therapy provider class plan to reflect its current practices to communicate with home infusion therapy providers about issues of interest and concern. It is therefore determined that BCBSM met the statutory goal for calendar years 2008 and 2009.

Cost Goal

The cost goal requires that the arrangements BCBSM maintains with each provider class will assure a rate of change in the total corporation payment per member that is not higher than the compound rate of inflation and real economic growth. Achievement of the cost goal is measured by application of the cost formula specified in the Act, which is estimated to be 1.0% for the period under review. As the rate of change in the total corporation payment per member for the home infusion therapy provider class has been calculated to be an increase of 6.0% over the two years being reviewed, BCBSM did not meet the cost goal stated in the Act for 2008 and 2009.

Overall Balance of Goals

In summary, although BCBSM did not substantially achieve one of the three statutory goals for the home infusion therapy provider class plan for the two year period under review, a change in the plan is not required because, as discussed in the body of this report, there has been competent, material, and substantial information obtained or submitted to support a determination that the failure to achieve all of the goals is reasonable, due to factors listed in Section 509(4).

Introduction

The purpose of this report is to determine whether Blue Cross and Blue Shield of Michigan (BCBSM) met the access, quality of care, and cost goals outlined in the Nonprofit Health Care Corporation Reform Act, MCLA 550.1101 et seq. (Act), with respect to the home infusion therapy provider class plan for the calendar years 2008 and 2009.

In addition to the final determination, this report will: define a provider class plan, explain the statutory review process, and provide a detailed summary of the data considered in reaching the determination as well as a statement of findings, which support that determination.

Provider Class Plans - Legal Background

Section 107(7) of the Act, defines a provider class plan as "a document containing a reimbursement arrangement and objectives for a provider class, and, in the case of those providers with which a health care corporation contracts, provisions that are included in that contract." Simply stated, a provider class plan is a document that includes measurable objectives for meeting the nonprofit health care corporation's access, quality of care, and cost goals outlined in the Act.

Section 504(1) of the Act requires BCBSM to contract with or enter into a reimbursement arrangement with providers in order to assure subscribers reasonable access to, and reasonable cost and quality of, health care services in accordance with the following goals:

1. BCBSM must contract with or enter into reimbursement arrangements with an appropriate number of providers throughout the state to assure the availability of certificate covered health care services to each subscriber. Section 502(1) of the Act specifically indicates that a participating contract with providers includes not only agreements in which the providers agree to participate with BCBSM for all BCBSM members being rendered care, but also agreements in which the provider agrees to participate only on a per-case basis. Participation with BCBSM means that a provider of health care services agrees to accept BCBSM's approved payment as payment in full for services provided to a BCBSM member.

2. BCBSM must establish and providers must meet and abide by reasonable standards of quality for health care services provided to members.

3. BCBSM must compensate providers in accordance with reimbursement arrangements that will assure a rate of change in the total corporation payment per member to each provider class that is not higher than the compound rate of inflation and real economic growth.

Section 509(4) of the Act requires the Commissioner of Financial and Insurance Regulation (Commissioner) to consider various types of information in making a determination with respect to the statutory goals. This information includes:

1. Annual reports filed by BCBSM, which pertain to each respective provider class;

2. Comments received from subscribers, providers, and provider organizations;

3. Health care legislation;

4. Demographic, epidemiological and economic trends;

5. Administrative agency or judicial actions; sudden changes in circumstances; and changes in health care benefits, practices and technology.

The Commissioner shall also assure an overall balance of the goals so that one goal is not focused on independently of the other statutory goals and so that no portion of BCBSM's fair share of reasonable costs to the provider are borne by other health care purchasers. After careful consideration of all of the information that was submitted or obtained for the record, the Commissioner must make one of the following determinations pursuant to Section 510(1) of the Act:

(a) That the provider class plan achieves the goals of the corporation as provided in Section 504 of the Act.

(b) That although the provider class plan does not substantially achieve one or more of the goals of the corporation, a change in the provider class plan is not required because there has been competent, material, and substantial information obtained and submitted to support a determination that the failure to achieve one or more of the goals was reasonable due to the factors listed in Section 509(4) of the Act.

(c) That the provider class plan does not substantially achieve one or more of the goals of the corporation as provided in Section 504 of the Act.

If the Commissioner determines that the plan does not substantially achieve one or more of the goals, without a finding that such failure was reasonable, BCBSM must transmit to the Commissioner within six months a provider class plan that substantially achieves the goals, achieves the objectives, and substantially overcomes the deficiencies enumerated in the findings. If after six months or such additional time as provided for in Section 512, BCBSM has failed to submit a revised provider class plan as stated above, the Commissioner must then prepare a provider class plan for that provider class.

Overview of the Home Infusion Therapy Provider Class Plan

The home infusion therapy provider class for BCBSM covers services provided by providers who are accredited in pharmacy, durable medical equipment, medical supplies and home infusion nursing. The scope of service includes administration of medications and nutritional solutions using intravenous, subcutaneous and epidural routes. The home infusion therapy benefit provides coverage for the in-home administration of infusion therapy services, regardless of whether the patient is confined to the home. There are no day or visit limitations for these services.

For the period 2008-2009, payments to home infusion therapy providers represented an average of 1.3% of the total benefit payments made to health care providers on behalf of BCBSM members. For the purpose of provider class plan reviews by the Office of Financial and Insurance Regulation (OFIR), paid claims data are categorized by nine geographic regions. A map, which depicts these geographic regions, is included in Attachment A.

Home infusion therapy providers are subject to certain qualification standards set by BCBSM. BCBSM's home infusion therapy provider class plan indicates providers must be accredited by either the Joint Commission of Healthcare Organizations or the Community Health Accreditation Program (CHAP) or the Accreditation Commission for Health Care (ACHC) in home infusion therapy services; participate under Medicare Part B for durable medical equipment and pharmacy services; meet specific staffing requirements; have provisions for emergency care and be able to deliver care within 24 hours of a physician's order; and have a system for delivery, storage, and maintenance of supplies and equipment.

Reimbursement for covered home infusion therapy services includes three components: pharmaceuticals, nursing services and medical supplies and solutions. The three components are reimbursed using the following methods:

- For each covered pharmaceutical, BCBSM pays the provider the lesser of the maximum allowable cost (MAC) or billed charge, less member deductibles or copayments. If there is no BCBSM MAC price available for the drug provided, BCBSM will pay the lesser of a discounted Average Wholesale Price (AWP), or the provider's charge, less applicable copayments and deductibles. BCBSM will reimburse the provider according to the applicable BCBSM MAC or AWP that is in effect on the date the covered service is rendered.

- For covered DME or medical supplies, BCBSM will pay the lesser of the provider's charge or the bundled per-diem in effect on the date of service, less member deductible and copayments. The bundled per-diem is the fee allowed for each day of qualified infusion related therapy, and is indicated on the BCBSM Home Infusion Therapy (HIT) Provider Rate Schedule. The per-diem is payable only on days when the patient is receiving actual infusion of medications through intravenous or other

authorized drug delivery routes. The per-diem covers all services not included in the pharmaceutical or nursing service component for each date of service. The per-diem includes but is not limited to the following: durable medical equipment, medical supplies, patient education, line maintenance, dressing changes, and solutions required to administer infusion products.

- For each covered nursing visit, BCBSM will pay the provider the lesser of the billed charge or the maximum payment amount published in the HIT Provider Rate Schedule less member deductibles and copayments. The maximum payment is based on the portion of the 2006 bundled per-diem that is attributable to nursing visits. Nursing visits are limited to a weekly maximum.

During the review period, home infusion therapy providers could participate with BCBSM only under its formal participation program. A formally participating provider has signed an agreement to accept BCBSM reimbursement as payment in full, excluding applicable co-payments or deductibles, for all covered services rendered to BCBSM members by the provider.

BCBSM is required to include as part of each provider class plan its objectives toward achieving the goals specified in the Act. BCBSM's objectives with regard to the home infusion therapy provider class plan are to:

Access:

- Provide direct reimbursement to participating providers who render medically necessary, high-quality services to BCBSM members.
- Communicate with participating providers about coverage determinations, billing, benefits, provider appeals processes, BCBSM's record keeping requirements and the participating agreement and its administration.
- Maintain and periodically update a printed or web site directory of participating providers.

Quality of Care:

- Ensure BCBSM members receive quality care by requiring participating providers to meet BCBSM's qualification and performance standards.
- Meet with specialty liaison societies to discuss issues of interest and concern.
- Maintain and update, as necessary, an appeals process that allows participating providers to appeal individual claims disputes regarding utilization review audits.

Cost:

- Strive toward meeting the cost goal within the confines of Michigan and national health care market conditions.
- Provide equitable reimbursement to participating providers through the reimbursement methodology outlined in the participation agreement

History of the Home Infusion Therapy Provider Class Plan

BCBSM first filed the home infusion therapy provider class plan with OFIR pursuant to Section 506(1) of the Act on March 12, 1996.

Section 506(2) states:

> "Upon receipt of a provider class plan, the commissioner shall examine the plan and shall determine only if the plan contains a reimbursement arrangement and objectives for each goal provided in Section 504, and, for those providers with which a health care corporation contracts, provisions that are included in that contract."

Section 506(2) further states:

> "For purposes of making the determination required by this subsection only, the commissioner shall liberally construe the items contained in a provider class plan."

Since the home infusion therapy provider class plan met the filing requirements of Section 506 of the Act stated above, OFIR retained the home infusion therapy provider class plan and it was placed into effect pursuant to Section 506(4).

On June 24, 1996, BCBSM amended all of its non-hospital, non-physician provider class plans, including the home infusion therapy plan, to include an appeal process for utilization review audits performed by the corporation. This amendment to the home infusion therapy provider class plan was made by BCBSM in accordance with Section 508(1) of the Act.

The home infusion therapy provider class plan was modified by BCBSM on December 26, 1997, July 26, 2000, August 14, 2006 and February 13, 2007. In 1997, BCBSM modified its appeal process for its non-hospital, non-physician provider class. In 2000, BCBSM modified its qualification standards and the reimbursement mechanism for HIT covered services. In 2006, the home infusion therapy provider class plan was modified to update BCBSM's objectives toward meeting statutory goals and the HIT qualification standards. BCBSM again modified the home infusion therapy provider class plan in 2007 to include the Accreditation Commission for Health Care as an approved accrediting body under BCBSM's qualification standards.

Review Process

On January 21, 2011, the Commissioner issued Order No. 11-003-BC, which provided written notice to BCBSM, health care providers, and other interested parties of his intent to make a determination with respect to the home infusion therapy provider class plan for calendar years 2008 and 2009. Order No. 11-003-BC also called for any person with comments on matters concerning the provider class plan to submit such comments to OFIR in accordance with Section 505(2) of the Act. Section 505(2) requires the Commissioner to establish and implement procedures whereby any person may offer advice and consultation on the development, modification, implementation, or review of a provider class plan. Requests for written testimony on BCBSM's home infusion therapy provider class plan were sent to all those on OFIR's interested persons list for the home infusion therapy provider class and posted on OFIR's website, providing interested parties three months to prepare and submit testimony.

Summary of Written Input:

Requests for written testimony regarding the home infusion therapy provider class plan were sent to those on OFIR's interested persons list and posted on OFIR's website. After querying its membership, the Michigan Pharmacists Organization (MPA) provided comments to OFIR with respect to the HIT provider class plan.

MPA believes that BCBSM has entered into a sufficient number of participation agreements with HIT providers. MPA supports BCBSM's any willing provider approach to participation as a HIT provider. Yet, MPA states that some HIT providers have experienced challenges with some of BCBSM's documentation requirements, especially the placement of significant administrative burdens on providers to obtain physician documentation above and beyond the legal prescription requirements specified by the State of Michigan Public Health Code, the State of Michigan Board of Pharmacy Administrative Rules and the Drug Enforcement Administration Code of Federal Regulations. MPA feels as though BCBSM's requirements force HIT providers to police physician prescribing under the fear that BCBSM will require HIT providers to refund monies to BCBSM, even where there is no question regarding the appropriateness of the HIT services provided.

MPA states that over the past few years, BCBSM has significantly increased its communication of provider requirements in its monthly publication of the *Record* and in Web-DENIS, yet BCBSM has not pro-actively worked with the prescriber community in a collaborative manner to address issues and formulate solutions. MPA desires to be BCBSM's source of input for HIT providers to address program issues and policy and program requirements prior to finalizing, announcing and implementing change. BCBSM does hold quarterly pharmacy provider liaison meetings but these meetings do not typically address HIT services or durable medical equipment (DME) policies, despite the fact that many Michigan pharmacies provide HIT and DME services. MPA recommends BCBSM work collaboratively with MPA and the Michigan Home Health Association (MHHA) to address provider issues.

MPA believes BCBSM's quality requirements are very basic and are primarily related to facility and clinician licensure and accreditation. The opportunity exists to advance the quality requirements of the HIT program, which ultimately can improve patient care and improve health care outcomes.

MPA states BCBSM processes provider claims in a reasonable time frame, but does not offer a process to address unique situations prospectively, again placing providers in a position of financial risk if claims are not paid in full or refunds are requested. All medical necessity, audit and reimbursement considerations are addressed after services are provided.

Expanded quality requirements should be included in the next HIT provider class plan (e.g. patient outcomes, after-hour services resulting in avoided hospital days or emergency department visits, catheter infection rates) and HIT providers should be both incentivized and rewarded for advancing patient care, patient outcomes and the quality of HIT services provided. MPA states that providers should also be compensated for providing prescribed care and realizing positive therapy outcomes, rather than being financially penalized for technical documentation errors of omission or commission. BCBSM should also provide an avenue for providers to obtain prior authorizations for patient care situations which are not clearly addressed within provider guidelines to minimize financial risk. Finally, a primary BCBSM HIT provider contact should be identified and empowered to act as a liaison to the HIT provider community, on an ongoing basis.

With respect to HIT reimbursement, MPA believes the opportunity exists for BCBSM to update and enhance the reimbursement methodology described in the participation agreement to be more equitable and fair to providers and to fully comply with standardized coding and claiming Health Insurance Portability and Accountability Act (HIPAA) requirements.

MPA desires that OFIR progressively consider the methodology in which BCBSM's reimbursement arrangements, cost and utilization is assessed. Reimbursement arrangements with providers should not be limited solely to "a rate of change in total corporation payment per member that is not higher than the compound rate of inflation and real economic growth" for two reasons. First, increased utilization should be appropriately factored into the cost evaluation equation because HIT is a very favorable treatment option as opposed to other settings of care. HIT utilization should be encouraged and should not negatively impact the provision of competitive reimbursement to HIT providers. Second, the compounded rate of inflation does not accurately reflect the inflation rate of pharmaceuticals and medical products, which represent approximately three-fourths of the HIT spending, considering the three-component HIT reimbursement model, which includes medications (74%), therapy per diems (19%) and nursing services (7%). For these reasons, MPA agrees with BCBSM's performance assessment that its failure to meet the cost goal for the HIT provider class was reasonable in accordance with Section 510(1)(b) of the Act.

MPA and the HIT provider community recommend the following reimbursement considerations be adopted by BCBSM to provide fair and equitable reimbursement (methodologies):

1. Clearly define in the participation agreement that the methodology of compensation for HIT providers consists of three subcomponents as follows:

    a. Per Diem – all necessary supplies (i.e., infusion pumps, administration sets, syringes, etc.) and the very substantial service components are reimbursed through a daily rate.
    b. Medications – all medications are coded, billed and reimbursed separately from per diem rates.
    c. Home Infusion Nursing Visits – all services provided by the high-tech home infusion nurse directly to patients in their residences or other alternative sites are coded, billed and reimbursed separately from per diem rates.

2. Fully reimburse providers for all medications used in the compounding and provision of HIT services, inclusive of the primary medication(s), diluents and vehicles used in pharmaceutical compounding and legend pharmaceutical flush solutions. Specifically, reimbursement for the nonprimary medications should not be "bundled" in the therapy per diems because altering the definition of claim coding is not HIPAA compliant. Furthermore, these are direct pharmacy costs that MPA believes should be directly reimbursed.

    For purposes of coding, billing and reimbursing separately from per diem rates, as required by HCPCS per diem code descriptions, MPA recommends that the following definition of a drug be included in the participation agreement as obtained from the Federal Food, Drug and Cosmetic Act (21 U.S.C. 353(b)):

    i. A prescription drug (also called legend drug) for which this legislation requires that the manufacturer's label contains, at a minimum, the symbol "Rx only" or the label, "Caution: Federal law prohibits dispensing without prescription" as required by this legislation prior to amendment by the Food and Drug Modernization Act of 1997, which means that it shall be dispensed only upon a prescription of a practitioner licensed to administer such a drug "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use" (Section 503(b)(1)) and further that

    ii. A drug "means (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(d) articles intended for use as a component of any article specified in (a), (b) or (c)."

3. Fully reimburse providers for all specialty infusion nursing services provided and not "bundle" in the therapy per diems because altering the definition of claim coding is not HIPAA compliant. Nursing visits must be coded and reimbursed separately.

4. BCBSM needs to recognize that each of the aforementioned components of reimbursement is important to allowing home infusion providers to continue performing their services. However, if marketplace or government actions result in reduced margins from one of these components, BCBSM should offer organizations the opportunity to reassess whether reimbursement for the remaining components is sufficient to ensure continued services. Of particular concern in today's marketplace are attempts to significantly alter the traditional reimbursement mechanisms for medications. MPA recommends that BCBSM's participation agreement recognize that changes in reimbursement levels to any of these subcomponents may cause providers to reassess the adequacy of total compensation. Therefore, the agreement must consider these issues as a whole and view them as integral to the sustained provision of these cost-effective and high-quality home infusion services.

5. MPA recommends that BCBSM's participation agreement clearly and comprehensively define medication reimbursement methodology parameters.

    a. Medications supplied in vials labeled for single dose use (containing no preservatives nor approved for multiple dose use), for which only a portion is prepared for the patient, shall be reimbursed by BCBSM at the full agreement rate for the entire contents of the opened vial. Each prescription medication dispensed pursuant to the provider agreement shall be coded and identified according to its unique National Drug Code (NDC). Providers shall bill and BCBSM shall reimburse according to the Average Wholesale Price (AWP) or published BCBSM Maximum Allowable Cost (MAC) of the dispensed medication, plus or minus the percent discount or MAC, if applicable as specified in the agreement, for the dispensed medication. The AWP shall be the Average Wholesale Price, in effect as of the date of service (according to the Published AWP Source), of the dispensed medication, as identified by its unique NDC and published by one of the following Published AWP Sources:

        i. Facts & Comparisons Medispan
        ii. First Databank Bluebook
        iii. Medical Economics Redbook.

    b. Similarly, the MAC shall be the medication price in effect as of the date of service according to the designated reference provided by BCBSM.

    c. For the purposes of billing and reimbursement under this Agreement, AWP shall be determined by the Published AWP Source selected in the above

section. The Published AWP Source may not be changed without mutual written agreement of the parties hereto. Only one Published AWP Source may be selected at any given time, and shall apply to all medications dispensed pursuant to this Agreement.

d. In the event of a change in (i) the calculation methodology utilized by the Published AWP Source for the purposes of determining or publishing AWP, or (ii) any federal or state laws, government regulations, Medicare or Medicaid rules or payment policies as such may be related to AWP or that would necessitate a substantial change in methodologies for reimbursement of medications, the parties hereto shall negotiate in good faith to amend this agreement so as to preserve the economic expectations of the parties at the time they entered into this Agreement. The parties shall meet and confer within ten days of either party notifying the other party that a change of the type described above has occurred to negotiate such an amendment. There shall be no change in AWP pricing during the negotiation period unless and until both parties reach an agreement. If there is an agreement between the parties on how to preserve the economic expectations of the notifying party, the effective date of the resulting amendment shall be the first day of the second calendar month commencing after the date of the amendment. Should the parties not reach agreement on how to preserve the economic expectations of the notifying party within 30 days of the notification, the parties agree to invoke the arbitration or dispute resolution process set forth in this Agreement.

6. MPA recommends that medication shortages and limited availability be explicitly defined in the program agreement. Example language; in the event of an acute shortage and/or limited availability of a particular medication product, such medication shall be billed and reimbursed at an amount equal to provider's billed charges using AWP as opposed to MAC.

7. MPA recommends that the medication wastage policy be explicitly defined in the provider agreement. For example, the delivery schedule for all supplies and medications shall be based primarily on the stability of the prescribed medication. The responsibility for communication regarding medication changes and cuts lies with the physician, patient and caregiver. Up to seven days of supplies and medication which have been prepared and/or delivered in good faith by provider shall be reimbursed by BCBSM at the full Agreement rate.

Discussion of Goals Achievement/Findings and Conclusions

Access Goal:

The access goal in Section 504(1) of the Act states that "[T]here will be an appropriate number of providers throughout this state to assure the availability of certificate-covered health care services to each subscriber."

In order to achieve compliance with the access goal, BCBSM needs to be able to assure, that in any given area of the state, a BCBSM member has reasonable access to home infusion therapy services covered under the terms of that member's certificate whenever such treatment is required. In analyzing BCBSM's performance on the access goal, OFIR staff examined several aspects of how access to home infusion therapy services could be obtained, including the formal participation rates of providers, to get an overall picture of how well BCBSM was assuring the availability of certificate-covered health care services to each member throughout the state.

BCBSM states that HIT providers are not licensed by the state of Michigan, BCBSM's participation rates are based on the total number of BCBSM registered HIT providers. As such, unless one of the registered HIT providers decided to no longer participate with BCBSM, BCBSM's participation rate is always 100%. The following information, supplied by BCBSM in December 2010, shows the number of Michigan registered and participating home infusion therapy providers and membership by geographic region for calendar years 2007 through 2009:

Home Infusion Therapy Provider Class Plan
Formal Participation Rates

Formal Participation Rates	2007	2008	2009
Formally Participating	37	36	37
All Registered Providers	37	36	37
Formal Par Rates	100%	100%	100%

MPA was asked whether it had a list of HIT providers so OFIR might better assess whether BCBSM's participation rates are accurate. Although MPA indicated it would look into the matter, no response from MPA was received during the course of this review.

In order to assess how the participation rates of home infusion therapy providers affect BCBSM member access to care, BCBSM provided the location of participating and registered providers by county for 2009. When looked at on a regional basis, it appears that the majority of HIT providers are located in southeast Michigan with most other regions besides the Lansing-based region having at least 2 available providers to serve BCBSM members. OFIR is not aware of any complaints from BCBSM members having difficulty in obtaining any necessary care.

MPA has expressed concern that HIT providers have experienced challenges with some of BCBSM's documentation requirements, especially the placement of significant administrative burdens on providers to obtain physician documentation above and beyond the legal prescription requirements specified within the State of Michigan Public Health Code, the State of Michigan Board of Pharmacy Administrative Rules and the Drug Enforcement Administration Code of Federal Regulations. MPA does not feel HIT

providers should be placed in the position of "policing physician prescribing" to avoid being subject to refund requests from BCBSM through its audit process.

BCBSM states that the sources identified by the MPA pertain solely to medications and do not apply to the other services HIT providers render (e.g. nursing services and supplies). The purpose of the sources noted above is to ensure that dispensed medications are prescribed by licensed physicians while BCBSM's requirements focus on not only that but on other quality indicators. BCBSM states it has a legal obligation under the Act to ensure that its members receive quality care at a reasonable cost so BCBSM is well within its legal rights to require more than what is required by the above sources. Moreover, BCBSM has no other option but to enforce these requirements via HIT providers as they are paid for their services – not the physicians who prescribe them. BCBSM contends this approach is no different from what is required under the Michigan Board of Pharmacy Administrative Rules, which holds the pharmacist liable – not the prescriber – when the pharmacist fills a prescription that does not meet the documentation requirements of the State Board of Pharmacy's Administrative Rules.

BCBSM states it does not feel the current requirements are unreasonable. The requirements are easy to meet and are not specific to HIT providers. Any time a physician orders durable medical equipment, prosthetics and orthotics or home infusion therapy services, the provider fulfilling the order must have a certificate of medical necessity in the patient file. The certificate must include the following: patient identification information; physician's name, address and telephone number; diagnosis related to the services or items provided; estimated duration of need and frequency of use; description of the patient's condition with details to substantiate the necessity of the services or items provided; physician's signature and date; diagnostic assessment; and, dosage, infusion time, fluids, frequency and duration of medication, the type or route of infusion administration, required equipment and supplies, nursing orders that include frequency of visits, flushes, line changes, IV restarts and other treatment orders, type of lab specimens the nurse needs to obtain from the member and lab tests for which the physician is requiring specimens.

BCBSM contends that all of these requirements enable BCBSM to ascertain that its members are receiving quality of care and the rendered services are, in fact, necessary. BCBSM does not believe, contrary to MPA's letter, that these requirements are rigidly applied in every case. BCBSM's auditors have the discretion to not penalize the provider where the records do not include, for example, all of the required physician information.

BCBSM's communication efforts also impact access to care as it helps establish and maintain a good rapport with participating providers.

BCBSM distributes to all providers a publication called the *Record*. This monthly publication contains current information relating to billing, reimbursement, group-specific benefit changes, day-to-day business information and medical criteria modifications. The

Record was created with input from provider focus groups as an ongoing effort to improve communications with providers and to make BCBSM information more accessible to them.

As part of the review process, OFIR examined a copy of BCBSM's home infusion therapy provider manual obtained from BCBSM's Web-DENIS. The provider manual, revised in September 2005 and continuously updated online, includes information, such as participation requirements, patient eligibility requirements, admission verification and pre-certification, benefits and exclusions, criteria and guidelines for services, documentation guidelines, claim submission information, and sections describing audit information, claims appeals processes, utilization review, and how to obtain information from BCBSM's provider inquiry department.

BCBSM states it offers providers the options of speaking with provider service representatives, writing to its inquiry department and having a provider consultant visit provider offices to help guide and educate their staff. BCBSM trainers also educate providers with seminars on various topics such as how to use web-DENIS, benefits, claims processing and adjustments. Computer based training tools have also been developed to expand the reach of the training sessions.

BCBSM's web-DENIS system offers BCBSM providers an internet-based program via a secured provider portal on www.bcbsm.com. This new program provides quick delivery of contract eligibility, claims status, online manuals, newsletters, fee schedules, reports and other types of required information designed to make doing business with BCBSM easier. BCBSM designed the Internet site to promote secure, effective and personalized use of the Internet for existing web-DENIS users and to encourage new providers to begin to use web-DENIS.

In 2008, BCBSM introduced a new search tool, Explainer, to web-DENIS. Explainer offers more information than the previous search tool and includes medical, benefit and payment policy information. Payment policy information provides member cost-sharing and dollar maximums with detail available at the procedure and revenue code levels for selected time periods. Also during 2008, BCBSM simplified web-DENIS by standardizing the look of the screens for members' claims processed on the local and NASCO claims systems. In 2009, web-DENIS added new claims tracking and screen printing capabilities and information on members' other active coverage.

Another avenue for home infusion therapy providers to obtain needed information from BCBSM is CAREN^{+}, an integrated voice response system which provides information on eligibility, benefits, deductibles and co-payments. In 2005, CAREN^{+} became speech enabled so providers can enter contract numbers by voice or text, with additional voice capability enhancements introduced in 2006. New security measures were also added to CAREN^{+} to safeguard BCBSM's members' protected health information.

BCBSM has also instituted several provider affiliation strategy programs to foster an ongoing commitment to excellent performance and dialogue with providers. BCBSM states it promotes business relationship with providers so they will: 1) collaborate with BCBSM to improve the health status of patients and the quality and cost effectiveness of care; 2) help BCBSM deliver outstanding customer service to members; and 3) value BCBSM as a health plan of choice and recommend it to patients and others. The provider affiliation strategy focuses on increasing provider satisfaction and creating a strong relationship with providers by providing a prompt and accurate claims payment system, consistent, accurate and responsive service; timely and effective communication, and partnerships to promote and facilitate better health care.

During the two year period under review, BCBSM's key initiatives to improve provider experience were:

- New enrollment forms available on bcbsm.com for all BCBSM and BCN professional providers. BCBSM and BCN worked together to streamline their enrollment forms and expedite the processing of new applications or requests to change existing records

- BCBSM's electronic funds transfer/electronic remittance advice program. The program was mandatory beginning July 1, 2009 for all participating professional providers and included:

    - Automatic direct deposit of claims payments
    - Online vouchers that can be searched by patient name, contract, document or case number
    - Access for up to three years of online voucher history

- BCBSM's commitment to reduce the volume of paper claims. In an effort to reduce costs and help the environment, BCBSM began an intensive outreach program to remove barriers that prevent providers from submitting all their claims electronically.

BCBSM believes these changes and other future enhancements will increase provider satisfaction, which will improve participation and access to care.

BCBSM states the home infusion therapy program was designed to standardize and improve the management of HIT services while recognizing that advancements in medicine allow for infusion therapy rendered in the patient's home. Infusion therapy also continues to be rendered in the physician office setting and in the hospital inpatient and outpatient settings. HIT services were previously paid under the pharmacy, DME and home health care provider classes.

Findings and Conclusions - Access

In order to achieve compliance with the access goal, BCBSM needs to be able to assure that in any given area of the state a member has reasonable access to certificate-covered home infusion therapy services, whenever such services are required. The number of home infusion therapy providers participating with BCBSM in Michigan regions is at an acceptable level. The lack of complaints on file with OFIR regarding the inability of BCBSM members to access home infusion therapy throughout Michigan seems to illustrate access to such services is adequate. As such, it is determined that BCBSM generally met the access goal stated in the Act for calendar years 2008 and 2009.

Quality of Care Goal:

The quality of care goal in Section 504(1) of the Act states that "[P]roviders will meet and abide by reasonable standards of health care quality."

In analyzing BCBSM's performance on the quality of care goal, OFIR staff examined BCBSM's achievement of its quality of care objective, the methods BCBSM utilized in establishing and maintaining appropriate standards of health care quality, and BCBSM's methods of communication with home infusion therapy providers. We reviewed these factors to assure that BCBSM not only encouraged provider compliance with the expected standards of home infusion therapy services, but also that it kept abreast of new technological advances available to treat those BCBSM members that require such services. All of the above factors impact the quality of home infusion therapy services delivered to BCBSM members. The pertinent issues that were considered in reaching a determination with respect to the quality of care goal, based on the review of data provided by BCBSM and other sources during this review period, are described below.

BCBSM states the following factors impacted quality of care performance:

- BCBSM enforced accreditation requirements and qualification standards through the provider credentialing process. Providers who could not demonstrate compliance with BCBSM requirements were not allowed to participate.

- An appeals process is outlined and communicated to providers in the provider manual as well as in the HIT Participation Agreement. The process outlined the steps a provider may follow to dispute claims and audit decisions.

- Quality controls were used to ensure that providers maintained high standards of care. In addition, BCBSM was involved in many programs to improve the quality of care to its members and Michigan residents.

To ensure acceptable levels of care provided by home infusion therapy providers, BCBSM requires that these providers meet the participation qualifications and performance

standards listed on page three of this report. BCBSM states that provider qualification status is continually monitored to ensure subscriber access to competent providers who are not involved in fraud or illegal activities.

BCBSM also monitors provider performance through its utilization review process. Audits can determine if services were medically necessary and rendered in accordance with members' benefits. Audit findings during the two year period under review included the quantity reported was not substantiated, the documented services did not substantiate payment of full per diem and an overall lack of documentation to support patient receipt of the service.

During utilization review audits, paid claims data and the corresponding medical records are reviewed to ensure that home infusion therapy services were appropriate and the services rendered were performed for the appropriate indications, in appropriate settings and were accurately billed and paid. At the conclusion of the audit, a departure conference with the facility representative, led by a BCBSM auditor, provides preliminary findings identified in the audit. The departure conference also serves as an opportunity for education. Methods to enhance correct coding and billing practices are discussed and HIT providers are encouraged to build on existing strengths.

As noted below, BCBSM audited a total of eight home infusion therapy providers during the two year period under review.

Home Infusion Therapy Providers Audit Results

	2008	2009
Number of audits	1	7
Initial Identified Savings	$74,300	$2,400,600
Year-end Recoveries	$50,000	$1,419,100
Referred to CFI*	0	0

*Corporate Financial Investigations

The MPA believes that BCBSM is by far the most aggressive health carrier in the Michigan marketplace in the area of technical provider guidelines requirement adherence. MPA realizes that audits are a necessary part of business practices, however, MPA is concerned that the audit process has gone beyond fraud, waste and abuse discovery to applications of recoveries based upon technical flaws in prescribing practices as a means of monetary recoupment. Reasonable discretion should be exercised during the audit process as rather than a rigid application of technical requirements to justify provider refunds. Such a change in auditing would minimize the financial risk to providers. MPA desires to see audit efforts clarified, streamlined and directed toward endeavors that directly impact patient care.

BCBSM states that unlike other health carriers in Michigan, it is obligated under the Act to take steps to ensure that it meets the cost, quality of care, and access goals specified in

Part 5 of the Act. Key to meeting this obligation is the audit process, which is designed not only to identify fraud, waste and abuse, but also to support BCBSM's achievement of these goals. BCBSM's documentation requirements ensure that members receive only services that are, in fact, necessary and appropriate for the member's medical condition. This supports the goals delineated in the Act. BCBSM also is charged with the responsibility under its contracts with customers to monitor HIT providers to ensure they meet its customers' quality expectations.

The MPA noted that it believes HIT providers should be compensated for providing prescribed care and realizing positive therapy outcomes instead of being financially penalized for technical documentation errors of omission or commission. MPA also believes BCBSM should provide an avenue for providers to obtain prior authorizations for patient care situations which are not clearly addressed within provider guidelines to minimize provider financial risk.

BCBSM states that at this time, only physicians are eligible to receive incentives for patient care. If HIT providers wish to pursue this idea, as well as be allowed to preauthorize services, they should do so through the established liaison process BCBSM has with home health care and durable medical equipment providers.

Another measure of BCBSM's achievement of the quality of care goal includes BCBSM's ability to effectively communicate with providers. Given that the quality of care goal defined in the Act requires that "providers meet and abide by reasonable standards of health care quality," it is necessary for providers to be made aware of BCBSM's standards, for BCBSM to verify that its providers adhere to such standards and that BCBSM is responsive to provider inquiries, input, and appeals, as all of these factors impact the quality of home infusion therapy services given to BCBSM members.

MPA claims there is no opportunity to prospectively address unique issues HIT providers may have. BCBSM contends that HIT providers are always free to refer their issues to their BCBSM consultant or that HIT provider's day-to-day questions about billing, benefits and other issues can be sent to MACAdmin@bcbsm.com.

BCBSM states while it is happy to work with the MPA to identify and implement quality activities, it is not appropriate to use MPA as the primary source of input for the HIT provider class. HIT providers are owed and operated by pharmacies and hospitals so it is important to BCBSM that all HIT providers – not just those owned by pharmacies – be equally heard to ensure that BCBSM's policies and initiatives are fair and balanced. Also, BCBSM also receives complaints from providers that large organizations do not necessarily represent the interests of providers that are not members of such organizations. Given this, and the fact that there are only 37 HIT providers, BCBSM feels it is more appropriate to receive input from any HIT provider.

One of BCBSM's objectives for the home infusion therapy provider class plan is to meet with specialty liaison societies to discuss issues of interest and concern. BCBSM notes its

liaison process has changed considerably over the last several years due to changes in the corporate organization. BCBSM acknowledges that it did not meet directly with a HIT liaison group during the two year period under review. BCBSM states that inasmuch as HIT benefits include pharmacy services and medical care, there is no one area within BCBSM that can address all HIT issues. As a result, providers should send their concerns to their provider consultant who will forward them to the appropriate parties with BCBSM for consideration. BCBSM states that for future reporting, BCBSM can rewrite this objective in the HIT provider class plan to better reflect its communication practices with HIT providers.

BCBSM states that it maintains open communications with home infusion therapy providers through its monthly publications, provider manuals, and its formal appeal process. All participating home infusion therapy providers receive BCBSM's monthly publication of the *Record*. BCBSM states the issues discussed in this publication are those that often impact providers' practice patterns and the achievement of utilization performance standards. BCBSM also has regional field services representatives that are available for on-site, individualized provider education and to address problems and concerns. Providers also receive direct mailings from BCBSM announcing changes in benefit programs and requesting provider feedback and these types of issues.

BCBSM also maintains a provider appeal process for home infusion therapy providers. The purpose of the appeal process is to resolve claim or audit disagreements. The appeal process is periodically published in the *Record* and is outlined in detail in both the online provider manual and the home infusion therapy facility participating agreement.

There are many different levels of the appeals process. The provider starts with a routine inquiry to BCBSM and can follow with a written complaint asking for a reconsideration review. If the provider is not satisfied with the reconsideration, he or she may submit a written request for a Managerial-Level Review Conference. During this conference, BCBSM and the provider discuss the dispute in an informal setting and explore possible resolutions of the dispute.

If the provider is dissatisfied with the managerial-level review, the provider can continue with BCBSM's appeal process, appeal to OFIR, initiate legal action, or if medical necessity issues are in dispute, request an external peer review for medical necessity issues. If this review is decided in favor of BCBSM, the provider will pay the costs of the external review. If the review is decided in favor of the provider, BCBSM pays the costs. If the findings are partially upheld and partially reversed, BCBSM and the provider share the costs of peer review in proportion to the results. The decision of the external review organization on medical necessity disputes is final and binding on both the provider and BCBSM.

For disputes involving administrative, billing and coding disputes, a provider may request a review by an internal review committee. BCBSM's Internal Review Committee is composed of three members of BCBSM senior management. If providers are unhappy with the Internal Review Committee decision, they can appeal to BCBSM's Provider

Relations Committee. The Provider Relations Committee is a subcommittee of the BCBSM Board of Directors composed of BCBSM participating professionals, community leaders and BCBSM senior management.

Providers that go through BCBSM's appeals process and remain dissatisfied can appeal medical necessity issues and administrative and billing and coding issues to OFIR for an informal review and determination. If the provider remains dissatisfied, they can move to a contested case hearing pursuant to Section 550.1404(6) of the Act. Contested case hearing decisions are subject to appeal in the circuit court.

During the two year period under review, there were no new requests from HIT providers for a review and determination by OFIR.

BCBSM's 2009 quality initiatives included the patient-centered medical home program, the BlueHealthConnection® chronic condition management program and new online resources. These initiatives promote collaboration among BCBSM, providers and members to improve member health and the quality and cost effectiveness of care. These tools also help BCBSM deliver outstanding customer service to members and demonstrate value by promoting better health care options and outcomes.

Patient-centered medical home (PCMH) is an approach in which patients take an active role in their own health care, working closely with their primary care physicians (pediatricians, internists and family practice doctors) throughout the journey across the health care system. Doctors coordinate patients' health care by managing chronic conditions, including conditions that may require home infusion therapy services, tracking all medications, offering extended office hours and practicing ongoing health management to keep patients healthy and prevent complications.

Many studies have found that having a regular source of care with the same physician over time leads to better health and lower overall cost of care. BCBSM states that a 2004 report in the *Annals of Family Medicine* that concluded that if every American had a medical home, health care costs would decrease 5.6%, resulting in national savings of $67 billion per year and improved care quality.

During 2009, over 1,200 BCBSM participating physicians earned the PCMH designation, impacting nearly 2 million Michigan residents. Early results showed that PCMH practices had a 2% lower rate of adult radiology usage than non-PCMH practices, a 1.4% lower rate of adult emergency room visits than non-PCMH practices and a 2.2% lower rate of pediatric emergency room visits than non-PCMH practices.[1]

BlueHealthConnection® is a confidential program that gives members the information, tools and assistance they need to manage a chronic condition such as diabetes, heart failure, coronary artery disease, chronic obstructive pulmonary disease and asthma.

[1] "BCBSM's Patient-Centered Medical Home Program Reports Early Success," Blues News Direct, June 9, 2010.

Eligible members who choose to participate in this voluntary program receive one-on-one support from a registered nurse case manager, who helps the member better understand and manage his/her condition. Over the course of a few months, the nurse case manager works with the member to set goals and implement a plan to manage a chronic condition.

All BCBSM members have access to a variety of online tools to empower them to manage their health and make better health care decisions. The Succeed™ health assessment tool is a questionnaire that asks about health, lifestyle and behavior. It targets topics such as nutrition, weight, physical activity, stress, depression, tobacco use and alcohol use. Upon completing the health assessment, members receive a report on their current health behaviors and a tailored plan that offers specific, practical advice for improving their health where they need it most.

The plan may suggest one of the online coaching programs available to help members address their key health challenges, such as:

- Care® for your Health, a chronic illness self-management program
- Care® for Diabetes
- Balance®, a weight management and physical activity program
- Nourish®, a nutritional management program
- Care® for Your Back, a low back pain treatment program

Other online tools are also available to help members take charge of their health, including fitness videos that can be downloaded to an MP3 player, calculators, podcasts, healthy recipes and quizzes.

Findings and Conclusions - Quality of Care

In order to meet the quality of care goal, the provider class plan must assure that "providers will meet and abide by reasonable standards of health care quality." During calendar years 2008 and 2009, BCBSM required all home infusion therapy providers to meet its qualification standards for participation and maintained communication with home infusion therapy providers through its monthly publications, appeal processes, provider manuals and online resources. BCBSM acknowledged that one of its "standardized" objectives listed in all provider class plans to meet with specialty liaison societies is not commonly practiced with home infusion therapy providers. BCBSM stated it will rewrite this particular objective to reflect is current business practice to communicate with home infusion therapy providers about issues of interest and concern. As such, based on the information analyzed during this review, it is determined that BCBSM met the quality of care goal stated in the Act for the calendar years 2008 and 2009.

Cost Goal:

The cost goal in Section 504(1) of the Act states that "[P]roviders will be subject to reimbursement arrangements that will assure a rate of change in the total corporation payment per member to each provider class that is not higher than the compound rate of inflation and real economic growth."

After application of the cost formula found in Section 504 of the Act and using economic statistics published by the U. S. Department of Commerce, it is hereby determined that the measure that will be used to determine BCBSM's achievement of the cost goal shall be as follows:

> The rate of change in the total corporation payment per member for the home infusion therapy provider class for calendar years 2008 and 2009 shall not exceed 1.0%.

The pertinent issues that were considered in reaching a determination with respect to the cost goal are described below.

The cost goal formula, as stated in the Act, is

$$\frac{[(100 + I) \times (100 + REG)]}{100} - 100 = \text{Compound rate of inflation and real economic growth}$$

"I" is "inflation" which is the arithmetic average of the percentage change in the implicit price deflator for GNP over the two calendar years immediately preceding the year in which the Commissioner's determination is being made.

"REG" is "real economic growth" which is the arithmetic average of the percentage change in per capita Gross National Product (GNP) in constant dollars over the four calendar years immediately preceding the year in which the Commissioner's determination is being made. The cost goal formula, as stated in the Act, is

Given the December 2009 population data obtained from monthly population estimates published by the Bureau of Census, as obtained from the U. S. Census Bureau and economic statistics for the GNP and implicit GNP price deflator from the U. S. Department of Commerce, Bureau of Economic Analysis as published in October 2010 by the Federal Research Bank of St. Louis (research.stlouisfed.org/fred2/data/GNPC96.txt and research.stlouisfed.org/fred2/data/ GNPDEF.txt), the following calculations have been derived:

I = Inflation as defined in the cost goal formula:

% change in implicit GNP price deflator

2008	2.7
2009	0.2
2 yr. average	1.5

REG = Real Economic Growth as defined in the cost goal formula:

% change in per capita GNP in constant dollars

2006	0.9
2007	1.9
2008	(0.9)
2009	(3.8)
4 yr. average	(0.5)

Using the latest population and economic statistics available, the cost goal for the period under review is estimated to be 1.0%, as shown below:

Inflation = 1.5

Real Economic Growth = (0.5)

$$\frac{[(100 + 1.5) \times (100 + (0.5)]}{100} - 100 = 1.0\%$$

Section 517 of the Act requires BCBSM to transmit an annual report to OFIR, which includes data necessary to determine the compliance or noncompliance with the cost and other statutory goals. The report must be in accordance with forms and instructions prescribed by the Commissioner and must include information as necessary to evaluate the considerations of Section 509(4).

As stated in Section 504(2)(e) of the Act, the "'[R]ate of change in the total corporation payment per member to each provider class means the arithmetic average of the percentage changes in the corporation payment per member for that provider class over the 2 years immediately preceding the commissioner's determination." The cost and membership data for the home infusion therapy provider class plan for the calendar years 2008 and 2009, as filed with OFIR by BCBSM, are presented below. Cost data reflect claims incurred in the calendar year and paid through February 28th of the following year.

Total Utilization and Payment Experience

BCBSM Home Infusion Therapy Figures	2007	2008	2009	Average Yearly Rate of Change
Total Payments	$32,926,728	$37,282,897	$35,243,970	
Total Members	2,549,593	2,534,933	2,445,989	
Cost Performance				
Payments/1000 Members	$12,914.50	$14,707.65	$14,408.88	**6.0%**
Rate of Change (%)		13.9%	(2.0)%	**6.0%**

The two-year arithmetic average increase for the home infusion therapy provider class plan equals 6.0%. This increase is a result of a 4.2% increase in visits and a 1.5% increase in payment per visit.

BCBSM states that the major payout categories for HIT services, by type of service, included pharmaceuticals, miscellaneous home infusion therapy, enteral/parenteral therapy and nursing services. These categories comprised 64.7%, 19.1%, 9.6% and 6.4% of the total payment, respectively.

HIT Trends by Type of Service
2007-2009

Types of Service	Two Year Average Rate of Change			Three Year Payout	% of Total Payout	Percent Contribution to Trend
	Payments/ 1000 members	Visits/ 1000 members	Payment/ Visit			
Drugs	7.5%	NA	NA	$68,235,268	64.7%	80.0%
Enteral/Parenteral Therapy	-5.7%	NA	NA	$10,154,783	9.6%	-9.3%
DME and Medical Supplies	8.6%	NA	NA	$20,094,820	19.1%	27.0%
Nursing Services	1.7%	NA	NA	$6,795,236	6.4%	1.7%
All Others	48.3%	NA	NA	$173,488	0.2%	0.6%
Total	6.0%	NA	NA	$105,453,595	100.0%	100.0%

As illustrated above, drugs and DME and medical supplies were the drivers of trend. These services accounted for 80% and 27%, respectively of the cost growth and 83.8% of all BCBSM payments. The drug category included injected and infused drug therapies.

Cost and utilization data by region is detailed below. The percent of payout is significant in regions 1 (Detroit/Southeastern Michigan area) and 6 (Grand Rapids/Muskegon area) where over 50% of the 2009 HIT membership resides.

HIT Trends by Region - 2007-2009

Region	Two Year Average Rate of Change			Three Year Payout	% of Total Payout
	Payments/ 1000 members	Visits/ 1000 members	Payment/ Visit		
1	8.8%	4.0%	4.4%	$61,213,884	58.0%
2	6.9%	16.4%	-8.2%	$14,392,092	13.6%
3	25.0%	11.5%	13.6%	$5,398,676	5.1%
4	-12.3%	-10.5%	-3.4%	$3,769,415	3.6%
5	-32.6%	-41.5%	23.6%	$3,264,255	3.1%
6	1.5%	19.5%	-13.9%	$11,302,502	10.7%
7	21.1%	-2.8%	24.0%	$2,310,980	2.2%
8	3.8%	0.0%	6.8%	$2,760,524	2.6%
9	-5.6%	-4.1%	-1.7%	$1,041,267	1.0%
Total	6.0%	4.2%	1.5%	$105,453,595	100.0%

BCBSM states the HIT program was designed to control costs by:

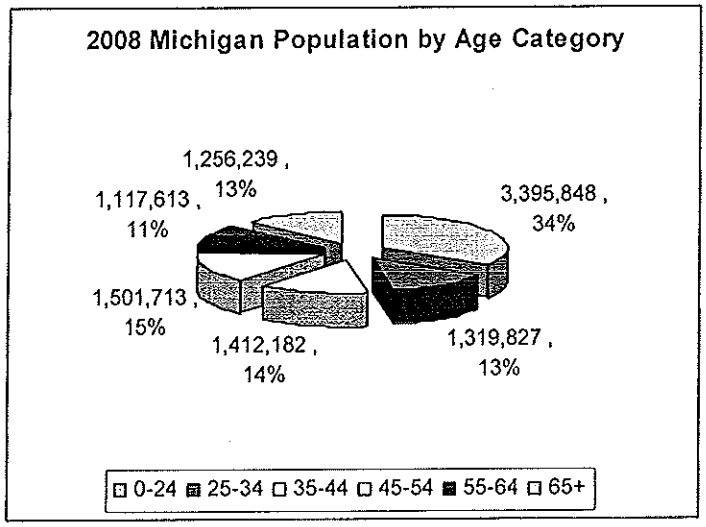
- Reimbursing the provider according to the applicable BCBSM maximum allowable cost (MAC) or discounted average wholesale price to manage drug costs.

- Managing the costs of DME and medical supplies through the use of the bundled per diem, which eliminates provider incentives to provide and bill for nonessential items.

- Reducing total infusion therapy costs by shifting care from the hospital inpatient and outpatient settings to the less costly home setting.

In addition, HIT services must be certified by the physician as medically necessary for the treatment of the condition, provided by a participating HIT provider, and prescribed by a physician within his or her scope of practice.

The characteristics of a population can significantly affect that population's consumption of health care resources. Michigan residents aged 45-64 comprised 26% of the state's overall population, slightly higher than the national average of 25%. Michigan's median age of 37.5 is slightly higher than the national median age of 36.6. The distribution of Michigan's 2008 population by age group is shown below:



BCBSM states that only 36.8% of Michigan's 2008 population (excluding Medicare and Medicaid recipients) has home infusion therapy benefits.

Home infusion has been proven to be a safe and effective alternative to inpatient care for many types of diseases and therapies. As Michigan continues to deal with an aging population (baby boomers) as well as high levels of obesity, the number of residents suffering from chronic, acute or terminal diseases continues to rise. Thus, the need for home related services such as home infusion therapy will continue to be increasingly important for patients desiring to receive services at home. Home infusion services are available to treat cancer, gastrointestinal diseases, chronic or terminal pain, immune deficiencies, cardiovascular disease or genetic diseases. Without a doubt, as Michigan residents with chronic conditions continue to have greater health care needs and are the most frequent users of health care services (regardless of age); the costs associated with these needs are disproportionately high.

Disorders of the immune system and serious infections were the top diagnoses by payment for HIT patients in 2009. New biological therapies are now available to treat a variety of previously untreatable disorders, including rheumatoid arthritis, multiple sclerosis, myasthenia gravis and cystic fibrosis. While these treatments are not cures, they can improve quality of life by slowing the progression of these diseases.

Total health care spending in 2009 represented 17.3% of the gross domestic product. The Center for Medicare and Medicaid (CMS) reports that part of the growth in expenditures for 2009 was due in part to projected faster growth in the use of services to treat the H1N1 virus and also in part to expected increases in subsidized coverage provided through the Consolidated Omnibus Budget Reconciliation Act (COBRA).

Driven by a focus on cost-effectiveness and cost-containment as well as the desire by patients to resume normal lifestyle and work activities while recovering from illness,

services such as home infusion therapy continues to expand. The National Home Infusion Association states that approximately 9 to 11 billion dollars a year are spent on home infusion therapy services by 700 to 1,000 infusion pharmacies nationwide. BCBSM states that the overall contribution of home infusion therapy to the overall health care system is much more significant in that the cost of care in an at home or non-hospital based setting is far less than the cost of inpatient treatment.

BCBSM's reimbursement methodology for home infusion therapy providers is described on pages 3 and 4 of this determination report. The MPA had several suggestions with respect to the payment for home infusion therapy services, including that BCBSM's reimbursement arrangements not be limited solely to the "rate of change in total corporation payment per member for each provider class that is not higher than the compound rate of inflation and real economic growth. MPA believes that increased utilization should be appropriately factored into the cost evaluation equation because HIT is a very favorable treatment option compared to more costly settings. HIT utilization should be encouraged and not negatively impact the provision of competitive reimbursement to HIT providers. MPA also feels the compounded rate of inflation does not accurately reflect the inflation rate of pharmaceuticals and medical products, which represent about three-fourths of HIT spending. As such, MPA concurs with BCBSM's performance assessment that there is competent, material and substantial information to support a determination that the failure to achieve the goal was reasonable in accordance with Section 510(1) of the Act.

It is believed MPA made these suggestions undoubtedly more to create a dialogue with BCBSM than any real anticipation that such items would be recommended as part of this review and determination. OFIR has no authority to change the formula the cost goal is based upon without a legislative change.

MPA has expressed its desire for BCBSM to make changes to both BCBSM's participation agreements and BCBSM's reimbursement methodology to address items such as the components of reimbursement, bundling of services, specialty infusion nursing services, and BCBSM's wastage policy. BCBSM states it already defines the components of reimbursement as pharmaceuticals, durable medical equipment, medical supplies and solutions and nursing visits. The pharmaceutical component includes the HIT Maximum Allowable Cost (MAC) list. BCBSM updates the HIT MAC list as new products need to be added or for price adjustments. BCBSM states that HIT providers can send inquiries regarding the HIT MAC list at any time to MACAdmin@bcbsm.com.

BCBSM states that MPA also suggested that BCBSM fully reimburse providers for all medications used in the compounding and provision of HIT services. BCBSM believes in the majority of cases, this is already being done. When multiple medications are combined for infusion and billed by the provider, BCBSM pays for each ingredient. Payment for the solution that is mixed with the medications is included in the per diem for DME and medical supplies. The exception is when the provider bills a "TPN", which is a combination of 12-15 different ingredients used for parenteral nutritional administration. When this occurs, the provider bills one code for the entire mixture and BCBSM pays an enhanced fee. Paying

for each ingredient separately, as the MPA suggested, would increase costs and create billing issues as there is not sufficient room on a claim form to list all 12-15 ingredients.

Moreover, BCBSM contends the way in which BCBSM reimburses HIT providers does not violate HIPAA. BCBSM states it is compliant with the Code Set Rules in that it accepts standard codes reported by HIT providers on their claims. The HIPAA rule clearly states that just because a code is established in a code set, this does not require a health plan to cover the procedure. BCBSM is permitted under the rules to deny codes and to use claim edits or other payment determinations to reimburse providers as permitted by its contractual agreements and reimbursement standards.

With respect to the HIPAA Standard Transaction Rules, to the extent it does "bundle" procedure codes, it is required to accurately reflect this bundling activity in its 835 remittance advice response to providers. To the best of BCBSM's knowledge, its 835 process for HIT providers is accurate and without issue.

MPA also requested that the FDA definition of the word "drug" be incorporated into the provider contract. BCBSM states that it appears the MPA seeks to have BCBSM pay providers using J codes rather than BCBSM's current practice of paying them using national drug codes (NDCs). J codes are high level codes that can include several types of drugs, and one price is paid no matter which of the drugs included in the code is administered to the member. NDCs are drug-specific and one price is paid for the drug represented by the code. By using NDC codes, BCBSM is better able to understand what drugs are being administered to its members and to more accurately pay providers for the drugs that are used. This helps BCBSM to achieve the quality of care and cost goals as it has documentation of what drugs are being utilized and what is driving HIT costs.

BCBSM states another matter suggested by MPA was that drugs be defined as including articles recognized by the Homoeopathic Pharmacopoeia of the United States. BCBSM does not cover homoeopathic drugs so to include such a reference in the definition of a drug would conflict with its benefit contracts.

BCBSM disagrees with MPA's suggestion that payment for specialty infusion nursing services be unbundled. Durable medical equipment, medical supplies and solutions and nursing visits make up the additional two HIT reimbursement components. Participating HIT providers are reimbursed per diem amounts representing provider costs for DME, supplies and solutions necessary to administer the infusion products. As such, BCBSM's HIT reimbursement policy does not allow separate reimbursement of "unbundled" individual items, such as diluents. The structure maintains consistency with HIPAA requirements since providers can still report codes that are considered inclusive of the per diem amounts, despite not being separately reimbursed. Also, if BCBSM's HIT reimbursement policy were modified to separately reimburse individual items, the per diem rates would be adjusted to reflect budget neutrality. Lastly, the nursing visits component is reimbursed separately from per diems and allows for payment of nursing visits to patients in their residences.

BCBSM believes it has adequately demonstrated that its failure to meet the cost goal was reasonable and notes that OFIR does not have the authority to require BCBSM to revise its HIT participation agreement absent a finding that BCBSM's failure to meet the cost goal was within its control.

Without a doubt, MPA's suggestions for revisions to BCBSM's participation agreement and reimbursement methodology would likely serve to increase payments to HIT providers at a time when utilization is also increasing. For BCBSM to act on these proposals, BCBSM would do so to its detriment as it would make any possible progress in meeting the statutory cost goal more unobtainable than already is.

There is a definite shift in the health care industry on both state and federal levels toward disease management programs as a way to controlling spiraling costs. Disease management aims at empowering participants to better manage and improve their own health, which in turn should help control costs of health care services. BCBSM states it has broadened its scope of medical care management design. BCBSM no longer directs all of its attention to provider costs and provider utilization but instead has developed member-focused health management programs.

As noted in the quality of care section of this determination report, BCBSM has developed and made available a number of online coaching programs and online tools to help members address their key health challenges and take charge of their health. These programs, over time, will encourage members to live more healthy lifestyles and in return, lessen health care costs associated with all BCBSM provider classes, including the home infusion therapy provider class.

Findings and Conclusions - Cost

Based on the cost information analyzed during this review, it is determined that BCBSM did not meet the cost goal stated in the Act for the home infusion therapy provider class during the two year period under review. This decision is based on the fact that the rate of change in the total corporation payment per member to the home infusion therapy provider class has been calculated to be 6.0% over the two years being reviewed and therefore exceeded the compound rate of inflation and real economic growth of 1.0%.

Nonetheless, there are other factors that impact BCBSM's ability to contain costs within the constraints of the cost goal specified in the Act. The most prominent factors include an aging population and the overall health status of Michigan residents. Michigan residents are living longer because of the development of cutting-edge technologies in medical diagnosis and treatment and the significant advances made in prescription drugs used to treat chronic illness. This increased longevity also increases the likelihood for Michigan residents to develop chronic conditions for which they seek out health care services. Also, many Michigan residents do not lead healthy lifestyles, which in turn, cause the development of debilitating conditions such as diabetes, cancer, hypertension, rheumatoid

arthritis, and coronary heart disease which require ongoing care, including home infusion therapy services.

Because of this, it is not necessary to require that a change to the current home infusion therapy provider class plan be filed pursuant to Section 511 of the Act. BCBSM is encouraged to continue its efforts to find new, innovative programs that instill responsible cost controls so that all the goals and objectives of the corporation can be achieved.

Determination Summary

In summary, BCBSM generally achieved two of the three goals of the corporation during the two-year period under review for the home infusion therapy provider class. Although the home infusion therapy provider class did not substantially achieve the cost goal, a change in the plan is not required because, as outlined above, there has been competent, material, and substantial information obtained or submitted to support a determination that the failure to achieve the cost goal was reasonable, due to factors listed in Section 509(4).

ATTACHMENT A